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Remarks

Applicant has herein amended claims 1, 22, 27 and 32. Twenty four (24) claims remain pending in the application: claims 1-3 and 15-35, of which claims 1 and 22 are independent. Applicant respectfully requests reconsideration of the pending claims, in view of the amendments above and comments below.

Claim Rejections - 35 USC § 103

In the final Office action mailed July 2, 2004, all claims were rejected under 35 U.S.C. 103(a) as unpatentable (obvious) over Rise US-5782798 in view of Fischell US-6006124 and either Boveja US-6269270 or Terry, Jr. et al US-5540730, with some of these rejections being further in view of various additional art.¹ Applicant will address this rejection in two parts: (1) the combination of Rise, Fischell and Terry, Jr. et al and (2) the combination of Rise, Fischell and Boveja.

The combination of Rise, Fischell and Terry, Jr. et al.

To overcome this rejection, applicant has amended independent claims 1 and 22 and dependent claims 27 and 32. The Office action states:

¹Claims 1-3, 15-18, 20, 22 and 26-34 were rejected under 35 U.S.C. 103(a) as unpatentable (obvious) over Rise US-5782798 in view of Fischell et al US-6006124 and either Boveja US-6269270 or Terry, Jr. et al US-5540730. Claims 19 and 23-25 were rejected under 35 U.S.C. 103(a) as unpatentable over Rise in view of Fischell et al and either Boveja or Terry, Jr. et al as applied to claims 1 and 22 above, and further in view of Zabara US-5540734 and Frankish et al (Neuropeptide Y, the Hypothalamus, and Diabetes: Insights into the Central Control of Metabolism - article). Claims 21 and 35 were rejected under 35 U.S.C. 103(a) as unpatentable over Rise in view of Fischell et al and either Boveja or Terry, Jr. et al, as applied to claims 1 and 22 above, and further in view of Schulman et al US-5193540.

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Terry, Jr. et al teaches that the stimulation of the dorsal motor nucleus of the vagus nerve provides treatment for patients with diabetes or metabolic disorders. (Note specifically column 3, lines 13-30 and column 2, lines 3-11.).... It would have been obvious to implant the electrodes of Rises [sic] device...adjacent the dorsal motor nucleus of the vagus nerve to control motility disorders associated with diabetes given Terry, Jr. et al's teaching.
Office action, paragraph 4.

Applicant has amended the claims to remove reference to stimulation of the dorsal motor nucleus of the vagus nerve. After entry of this amendment, all pending claims cover only stimulating the nucleus of the solitary tract, as discussed in detail below.

The combination of Rise, Fischell and Boveja

Applicant respectfully traverses this rejection and requests reconsideration in light of the comments below.

The pending independent claims (claims 1 and 22) cover "...applying...at least one stimulus to...the nucleus of the solitary tract" in order to prevent or treat diabetes. As explained further below, a person of ordinary skill in the art would not have been motivated to combine the cited references to arrive at the claimed invention. Furthermore, even if they were combined, these references fail to teach the claimed subject matter as a whole, as required by 35 U.S.C. 103.

Applicant finds no motivation to combine Rise and Fischell et al with Boveja. It is respectfully submitted that, per MPEP 2143.01 (emphasis in original):

[the] fact that references can be combined or modified is not sufficient to establish *prima facie* obviousness. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination.
In re Mills, 16 USPQ2d 1630 (Fed. Cir. 1990)

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Although the Examiner concludes that the combination of Rise and Fischell et al with Boveja makes obvious the claimed invention, he has not shown that there is any teaching or suggestion in any of the references, or in the prior art as a whole, of the desirability that would lead one with ordinary skill in the art to make the combination. "The Commissioner bears the burden of *showing*...some teaching, suggestion, or motivation to make the particular combination that was made by the applicant." *In re Raynes* 28 USPQ2d 1630, 1632 (Fed. Cir. 1993) (citations omitted; emphasis added). Such a suggestion has not been shown. The fact that a stimulus can be applied to the nucleus of the solitary tract to prevent or treat diabetes does not make the claimed invention obvious without the prior art suggesting the desirability of the claimed combination as a whole.

Combining elements "in a manner that reconstructs the applicant's invention only, with the benefit of hindsight, is insufficient to present a *prima facie* case of obviousness. There must be some reason, suggestion, or motivation found in the prior art whereby a person of ordinary skill in the field of the invention would make the combination. That knowledge cannot come from the applicant's invention itself." *In re Oetiker*, 24 USPQ2d 1443, 1447 (Fed. Cir. 1992) (citations omitted). The applicant submits that the Examiner's motivation to modify the references to arrive at the presently claimed invention derives from hindsight based on applicant's disclosure, as no "showing" has been made that the prior art suggests the desirability of the claimed combination and this interpretation of the knowledge in the art could be made only by hindsight.

Not only has a suggestion to modify or combine not been shown, it is evident that one of skill in the art would not have combined these references. The Boveja reference concerns "Adjunct (Add-On) Therapy of Dementia and Alzheimer's Disease." Applicant asserts that one

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of skill in the art would not combine this reference with Rise and Fischell et al. As explained below, the Boveja reference actually teaches away from the presently claimed invention.

Paragraph 4 of the Office action states that:

The [Boveja] reference teaches (Fig 1a) [sic] that the Nucleus of the Solitary tract has direct control over the hypothalamus.

Even if one of skill in the art understood from Boveja that the nucleus of the solitary tract has direct control over the hypothalamus, the Boveja reference would teach that person of skill in the art that the nucleus of the solitary tract also has direct control over other important structures in the brain:

*The vast majority of vagal nerve fibers are C fibers, and a majority are visceral afferents having cell bodies lying in masses or ganglia in the skull. The central projections terminate largely in the nucleus of the solitary tract which sends fibers to various regions of the brain, e.g., the hypothalamus, hippocampus, and amygdala. See FIG. 1 (from: Epilepsia, vol. 31, suppl. 2: 1990, page S2).
Boveja, column 2, line 66 - column 3, line 5.*

As such, *if one of skill in the art deduced from Fig. 1 that the nucleus of the solitary tract would affect "direct control over the hypothalamus", they would also understand that stimulation would also affect, e.g., the hippocampus, amygdala, dorsal raphe nucleus, and parabrachial nucleus. If this person of skill in the art were seeking direct control of the hypothalamus, and presumably did not want to cause massive side effects due to simultaneously controlling many other areas of the brain, Boveja would lead them away from the invention.*

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Paragraph 4 of the Office action also states:

It would have been obvious to implant the electrodes of Rises [sic] device adjacent the Nucleus of the Solitary Tract to control the hypothalamus and the production of Insulin given Boleja's [sic] teacher [sic]....

What exactly is meant by "Boleja's [sic] teacher [sic]" is unclear. If the Examiner meant that Boveja teaches locating electrodes adjacent the nucleus of the solitary tract, it would be instructive to know where the Examiner finds this teaching in Boveja, as applicant could find no such teaching. Applicant found that Boveja *mentions* cranial and peripheral nerve stimulation, *describes* only vagus nerve stimulation, but does not mention or suggest stimulating the nucleus of the solitary tract.

Perhaps, by "Boleja's [sic] teacher [sic]", the Examiner meant that Boveja teaches stimulating the nucleus of the solitary tract to control the hypothalamus and the production of insulin. The first problem with such an argument is that, as described directly above, Boveja does not teach stimulating the nucleus of the solitary tract.

The second problem with this argument is that Boveja doesn't suggest or even mention, let alone teach, the production of insulin or how to control the production of insulin. Once again, it would be instructive to know where the Examiner finds this teaching in Boveja, as applicant could find no such teaching.

The third problem with this argument is that Boveja doesn't suggest controlling the hypothalamus via the nucleus of the solitary tract, but rather mentions "activation" of the hypothalamus via peripheral (i.e., TENS) or cranial (e.g., vagus) nerve stimulation, (col. 3, lines 6-8):

An activation of higher-level areas, e.g. the hippocampus and hypothalamus, by TENS or cranial nerve (such as vagal nerve) stimulation might be transmitted by afferent nerve fibers....

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The fourth problem with this argument is that Boveja doesn't even "teach[] (Fig 1a) that the Nucleus of the Solitary Tract has direct control over the hypothalamus", as described in detail earlier.

Further, a combination of these references would not result in the present invention. While it is clear that a combination of Rise and Fischell with Boveja would not result in the present invention (since, for instance, there is no suggestion or motivation to apply a stimulus to the nucleus of the solitary tract to prevent or treat diabetes), it also appears that the intended function of the references would be destroyed if they were combined, making these references not properly combinable (see MPEP 2143.01: "The proposed modification cannot render the prior art unsatisfactory for its intended purpose"). For instance, Boveja's intention is to treat "dementia including probable Alzheimer's disease via afferent stimulation" while Rise's intention is to treat "eating disorders by brain stimulation and drug infusion". Were Rise to adopt Boveja's teachings, for instance, he would treat dementia rather than eating disorders, and vice versa. Therefore, for these additional reasons, one of skill in the art would not be motivated to make the suggested combination.

Even if all the claimed limitations were disclosed or suggested by the cited references (which they are not, as described above), the Federal Circuit has held that a reference does not render the claimed combination *prima facie* obvious if "the purpose of [the reference] is different from that of [the claimed invention]." *In re Fine*, 5 USPQ2d 1596 (Fed. Cir. 1988). As has been shown, the purpose of Boveja is very different from that of the present application. In other words, Boveja does not contemplate the purposes of the claimed invention, and the purpose of Boveja is different from that of the claimed invention. Thus, Boveja, alone or in combination with Rise and Fischell, does not render the claimed combination *prima facie* obvious.

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For the various reasons explained above, *prima facie* obviousness has not been established for independent claims 1 and 22 as amended, and the Rise, Fischell and Boveja references do not render the claimed invention obvious. Therefore, it is believed that claims 1 and 22, and the remaining pending claims, which all depend directly or indirectly from claim 1 or 22, are in condition for allowance. Acknowledgment of the same is earnestly solicited.

Conclusion

All pending claims depend directly or indirectly from independent claim 1 or 22. As such, applicants respectfully request consideration of Independent claims 1 and 22, and their dependent claims, in light of these remarks. Indication of allowance of the pending claims (claims 1-3 and 15-35) is earnestly solicited. In the alternative, if it is deemed that the claims are still not in condition for allowance, entry of this amendment is requested.

The Examiner is invited to telephone the undersigned, Laura H. Bishop, at his convenience should any issues remain after consideration of this response, in order to permit early resolution of the same.

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Respectfully Submitted,

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